Bio Start-ups: “Doing Business” With the NIH

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Why Do Business With NIH?

- Annual budget of $33.1 billion (FY16)
- ~10% of funding for intramural research
- 6,000 intramural scientists / 18,000 staff / 2,000 projects
- Basic & clinical research discoveries
- Collaborations with industry & academia
- Partners commercialize into products
Your Six Top NIH Business Tips & Opportunities For Start-Ups

- In-licensing of NIH technology
- Research collaborations with intramural NIH
- Using pre-clinical / clinical NIH services
- Selling products / services to NIH
- Getting grants & contracts from NIH
- Utilizing NIH information sources
Tip #1: NIH Technology Licensing
Characteristics of the NIH Intramural Research Program “Pipeline”

- Novel, fundamental research discoveries
- “Supermarket” for research tools
- Collaborations (CRADAs) for basic or clinical studies
- Selected projects in early clinical trials
- Product sales by licensees: ~$ 6B
More Recent Product Approvals

- Angiotech: Taxus & Zilver (drug stents)
- Genzyme: Thyrogen (rTSH)
- Medimmune: Synagis (RSV mab)
- Millennium: Velcade (myeloma drug)
- Biogen Idec: Zevalin (NHL I_{131} mab)
- Amgen: Kepivance (KGF)
- Merck: Gardasil (HPV vaccine)
- Tibotec: Prezista (HIV protease drug)
Special Developments For Small Companies

- Start-up Express License Agreements
  -- Option & Exclusive licenses with low or deferred financial terms

- SBIR-TT Program
  -- Bundle of SBIR award & exclusive license to intramural technology
Start-Up Challenge Contests: Licensing to University Start-Ups

Partnerships with Center for Advancing Innovation & private foundations
Tip #2: NIH Basic Research Collaborations
NIH Research Collaborations

- “Internal Use” Research Tool Licenses
- Cooperative Research And Development Agreement (CRADA)
- Clinical Trial Agreement
- Specialized Development Services
- Training Programs
- Informal “official duty” collaborations
Tip #3: NIH Pre-Clinical & Clinical Research Services
Pre-Clinical Research: NCI Developmental Therapeutics Program

- Assay development for screening
- Synthesize small quantities of compounds
- Provide compound libraries & reagents
- Pharmacology and toxicology testing
- Formulation
- Clinical batch production
- Services open to NIH & non-NIH organizations
Clinical Trials At NIH
Clinical Center
Clinical Trials Programs at Cancer Therapy Evaluation Program (CTEP)
Clinical and Translational Science Activities

- Clinical and Translational Science Awards

Rare Diseases Research and Therapeutics

- Therapeutics for Rare and Neglected Diseases
- Office of Rare Diseases Research
- Bridging Interventional Development Gaps

Re-engineering Translational Sciences

- NIH Chemical Genomics Center
- Toxicology in the 21st Century
Tip #4: Selling Products To NIH
Selling Products To NIH

- Largest US consumer of bioscience reagents & instruments
- Blanket purchase agreements (BPA)
- NIH Central Storeroom
- NIH Research Festival (Bethesda & Ft. Detrick Maryland campuses)
- Biodefense & translational research initiatives
Tip #5: Getting NIH Grants & Contracts
NIH Grant & Contract Opportunities

- Over 80% of NIH budget as grants & contracts
- Applicants for most programs can be for-profit or non-profit
- SBIR / STTR must be at least 51% US owned
- Venture-backed firms now eligible for SBIR
- Non-dilutive funding
- Many R&D contracting opportunities

See https://oamp.od.nih.gov/DGS/reference-material-prospective-offerors-and-contractors
Small Business R&D Funding

**SET ASIDE**

**SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**
Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

- **3.0%** (FY16)
- **3.2%** (FY17)

**SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**
Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

- **0.45%** (FY16)
- **0.45%** (FY17)
SBIR / STTR: 3 Phase Program

**Discovery**

- **Phase I Feasibility Study**
  - Budget Guide: $150K for SBIR and STTR
  - Project Period: 6 months (SBIR); 1 year (STTR)

**Development**

- **Phase II Full Research/R&D**
  - $1M for SBIR and STTR, over two years

- **Phase IIIB Competing Renewal/R&D**
  - Clinical R&D; Complex Instrumentation/Tools to FDA
  - Many, but not all, IC’s participate
  - Varies-$1M per year; up to 3 years

**Commercialization**

- **Phase III Commercialization Stage**
  - NIH, generally, not the “customer”
  - Consider partnering and exit strategy early
Tip #6: Utilizing NIH Information Sources For Your Business
Useful Business Information

- **New Licensing Opportunities RSS Feed:**
  --- http://www.ott.nih.gov/rss/

- **NIH Guide To Grants & Contracts Listserv:**
  http://grants1.nih.gov/grants/guide/listserv.htm

- **RePORTER Database of Awarded Grants**
  --- http://projectreporter.nih.gov/reporter.cfm

- **Exhibiting Your Products at NIH Research Festivals**
  --- www.technicalsalesassociation.org
For Further Reading ....

“Partnering with the NIH: Now part of the ‘Value Proposition’ for start-ups”

And From the Bio Bootcamp ….

“Licensing the Technology: Biotechnology Commercialization Strategies Using University and Federal Labs”

(Chapter 14)